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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/897,465	07/03/2001	Baldomero M. Olivera	2314-236	7074

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EXAMINER
BUGAISKY, GABRIELE E

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 03/12/2003

7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/897,465	OLIVERA ET AL.	
	Examiner	Art Unit	
	Gabriele E. BUGAISKY	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12/20/2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) *9,10 and 16-18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8 and 11-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *3* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of PNIA in Paper No. 6 is acknowledged. The traversal is on the ground(s) that a particular class of conotoxins will share a conserved cysteine framework, disulfide bridging pattern and conserved molecular target. and that there is no serious search burden. . This is not found persuasive because while it is agreed that that the α-conotoxins share a general 3 dimensional structure and share a similar cysteine framework and disulfide bridging pattern, there indeed is a serious search burden. The Examiner is of necessity limited to the search tools at hand. While the generic formula of SEQ ID NO:1 has been searched, it is a burden to search for each specifically recited peptide . For search purposes, the Examiner does however, consider , a propeptide along with the mature protein, and, e.g., a modified amino acid (e.g., Pro,Trp) such as those recited in claims 12-15 to be the same as Trp. While a general word search and search of the subclass is performed, the Examiner disagrees with the Applicant's position, in that a search for the specific peptides must be made and that a computer search for more than a single specific peptide indeed constitutes a severe burden. The sequence databases are growing at an incredible rate, specific searches for each claimed sequences must be performed and the Examiner is not given unlimited search time and resources The search constitutes AT PRESENT a serious burden. The Examiner can only operate with the search tools currently available to her. The requirement is still deemed proper and is therefore made FINAL.

Claims 9-10 and 16-18 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 6.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Information Disclosure Statement

The listing of references in the specification (pages23-25) is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892 or by Applicants on PTO-1449, they have not been considered.

Claim Objections

Claims 12-15 are objected to because of the following informalities: they read upon non-elected subject matter.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1- 8 and 11-14 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for α-conotoxins in treatment of disorders associated with neuronal nicotinic receptor dysfunction, does not reasonably provide enablement for treatment of specific disorders with the conotoxin PnIa (SEQ ID NO:10) . The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. The specification disclosed that PnIA is specific for the α7.subunit of the nicotinic receptor. This receptor subunit does not appear to be uniformly distributed throughout the body. McIntosh *et al.* (references A-C of PTO-892) teach, for example, that the conotoxin Imi, which also is specific for the α7.subunit, has no effect on nicotine stimulated dopamine release (Example 5) Thus, one may reasonably conclude that any conotoxin which is specific for only the α7.subunit will have no effect on treatment for nicotine addiction, and furthermore, will only be useful in treatment of disorders in which the . α7.subunit is present in a certain tissue type.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 14 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. With respect to claim 14, it is unclear what is meant by "incorporated on the N-terminus". Does it mean that tyrosine now is the N-terminus, followed by glycine (aa 1 of SEQ ID NO:10), or does it mean that the tyrosine is inserted between aa1 and aa2?

It is unclear from claim 15 (and the claim from which it depends) how an added tyrosine as specified in claim 14 can be substituted by one or two tyrosines. If the tyrosine is replaced by iodine(s), then the claim does not further limit claim 14, as no tyrosine is present at the N-terminus. Did Applicants perhaps intend to recite "labeled" or "modified" rather than "substituted"?

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1 and 6 are rejected under 35 U.S.C. 102(e) as being anticipated by McIntosh *et al.* (US patent 5,780,433). The references teaches the use of the α- conotoxin MII to treat nicotine addiction. The reference is deemed anticipatory for the claimed subject matter because

the structure of MII (GCCACPVCHLEHSNLC) fits the formula of SEQ ID NO:1. A species anticipates a genus.

Claims 1 and 7 are rejected under 35 U.S.C. 102(e) as being anticipated by McIntosh *et al.* (US patent 5929034). The references teaches the use of the α- conotoxin MII to treat a mood disorder The reference is deemed anticipatory for the claimed subject matter because the structure of MII (GCCACPVCHLEHSNLC) fits the formula of SEQ ID NO:1. A species anticipates a genus.

Claims 1 and 7 are rejected under 35 U.S.C. 102(e) as being anticipated by McIntosh *et al.* (US patent 5929034). The reference teaches the use of the α- conotoxin MII to treat a mood disorder The reference is deemed anticipatory for the claimed subject matter because the structure of MII (GCCACPVCHLEHSNLC) fits the formula of SEQ ID NO:1. A species anticipates a genus.

Claims 1 and 7 are rejected under 35 U.S.C. 102(e) as being anticipated by McIntosh *et al.* (US patent 5922679). The reference teaches the use of the α- conotoxin MII to treat a psychosis, schizophrenia being specified. A person suffering from a psychosis *a priori* has a mood disorder The reference is deemed anticipatory for the claimed subject matter because the structure of MII (GCCACPVCHLEHSNLC) fits the formula of SEQ ID NO:1. A species anticipates a genus.

The applied references have a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the

inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 and 6 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent No. 5780433. Although the conflicting claims are not identical, they are not patentably distinct from each other because the treatment method of the patent is a species of instant generic claims 1 and 6.). The claims of the reference are directed to the use of the α- conotoxin MII to treat nicotine addiction.; the sequence of MII (GCCACPVCHLEHSNLC) fits the formula of SEQ ID NO:1. A species anticipates a genus.

Claims 1 and 7 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent No. 4780433. Although the conflicting claims are not identical, they are not patentably distinct from each other because the treatment method of the patent is a species of instant generic claims 1 and 6.). The claims

of the reference are directed to the use of the α- conotoxin MII to treat a mood disorder; the sequence of MII (GCCACPVCHLEHSNLC) fits the formula of SEQ ID NO:1. A species anticipates a genus.

Claims 1 and 7 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 5922679. Although the conflicting claims are not identical, they are not patentably distinct from each other because the treatment method of the patent is a species of instant generic claims 1 and 6.). The claims of the reference are directed to the use of the α- conotoxin MII to treat a psychosis which *a prior* is a mood disorder; the sequence of MII (GCCACPVCHLEHSNLC) fits the formula of SEQ ID NO:1. A species anticipates a genus.

Conclusion

No claims are allowed. A generic treatment of disorders regulated at neuronal nicotinic acetylcholine receptors comprising administration of the conotoxin PnIA is considered patentable subject matter.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gabriele E. BUGAISKY whose telephone number is (703)308-4201. The examiner can normally be reached on 8:15 AM- 2 PM, Tu & Th, 8:15 AM-1:30 PM, We & Fr.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher SF Low can be reached on (703) 308-2923. The fax phone numbers for

the organization where this application or proceeding is assigned are 703 308-4242 for regular communications and 703 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 708 308-0196.

Gabriele E. BUGAISKY
Primary Examiner
Art Unit 1653

March 9, 2003

GABRIELLE BUGAISKY
PRIMARY EXAMINER

Notice of References Cited	Application/Control No. 09/897,465	Applicant(s)/Patent Under Reexamination OLIVERA ET AL.	
	Examiner Gabriele E. BUGAISKY	Art Unit 1653	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
	A	US-5922679	07-1999	McINTOSH et al.	514/13
	B	US-5929034	07-1999	McINTOSH et al.	514/13
	C	US-5780433	07-1998	McINTOSH et al.	514/13
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

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3/7/02

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE		
	Application Number	09/897,465
	Filing Date	3 July 2001
	First Named Inventor	Baldomero M. OLIVERA
	Group Art Unit	1653
	Examiner Name	
	Attorney Docket Number	2314-236

Title of the Invention: **USES OF ALPHA-CONOTOXIN PEPTIDES**

INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

The material listed on the accompanying Information Disclosure Statement by Applicant form is cited in compliance with the provisions of 37 C.F.R. §§ 1.56, 1.97 and 1.98. Applicant respectfully requests that the Examiner consider these references with respect to the present application.

Copies of these references can be found with the parent application, U.S. Serial Number 09/219,446 (US6,265,541) and, accordingly, will not be resubmitted unless requested by the Examiner.

RESPECTFULLY SUBMITTED,					
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SIGNATURE			*DATE*	4 March 2002	
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